Exhibit 1

Medtronic, Inc. 29-Aug-06

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7133
FAX: (612) 334-4142

August 29, 2006

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 06- 35

Arthur D . Collins, Jr.
Chairman of the Board and Chief Executive Officer
Medtronic, Inc .
710 Medtronic Parkway
Minneapolis, MN 55432

Dear Mr. Collins:

During a May 18 - June 22, 2006, inspection of your establishment, Medtronic Neurological, located at 800 - 53rd Avenue NE, Minneapolis, MN 55421, our investigators determined that your firm manufactures implantable drug infusion and neurostimulation products to treat pain, movement disorders, and other medical conditions. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)] because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated under Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to implement procedures to ensure that a device's design input requirements are appropriate and address its intended use, including user/patient needs, as required by 21 CFR 820.30(c). Design input work for the 8731 Intrathecal Catheter has not resulted in development of a complete design specification for the Platinum/ Iridium (Pt/Ir) catheter tip bond. (For more detail on this deviation, see FDA-483 observation # 1 from the May 18 - June 22, 2006, inspection. Copy of FDA 483 attached.)

2 . Failure to conduct design validation using production units or their equivalents, as required by 21 CFR 820.30(g). Design validation testing of the Model 8731 Catheter was conducted with catheters manufactured with a Pt/Ir tip marker bonding process that was different than the process eventually used in production. (See FDA-483 observation #2.)

3. Failure to validate a process whose results cannot be fully verified by subsequent inspection and test as required by 21 CFR 820.75(a). For the 8731 Catheter, the Pt/Ir tip bonding process has not been validated. (See FDA-483 observation #3.)

4. Failure to control production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For the 8731 Catheter, the tip bonding manufacturing procedures contained:

- an **[redacted]** of the tip, and
- instructions to **[redacted]** equipment that was no longer in service. (See FDA-483 observation #4.)

5. Failure to implement corrective and preventive action procedures addressing the investigation of the cause of nonconforrnities relating to product, processes, and the quality system as required by 21 CFR 820.100(a)(2). Examples include:

a. Corrective / Preventive Action System (C/PAS) 747 (re: 8731 tip detachments) was closed with a root cause analysis that conflicts with information received in complaints. No additional C/PAS was opened to address the complaints and failures that do not fit the root cause analysis in C/PAS 747. (See FDA-483 observation #5a.)

b. Product Comment Report (PCR) 170998 reported an 8731 catheter tip detachment and stated that " . . .post-operative the patient showed pain in the left leg, which can be related with the remaining tip ." In conflict with this reported event, a Health Hazard Analysis and "TECH NOTE" concluded that none of the tip detachments were associated with adverse clinical or neurological consequences. (See FDA-483 observation #5b.)

c. System Correction Request (SCR) 877, which addresses pump motor stalls due **[redacted]** to failures in Synchromed EL implantable infusion pumps, was closed without evidence to support conclusions that were made. (See FDA-483 observation #5c.)

6. Failure to-implement changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5). C/PAS 747 called for a redesign of the catheter tip and a new product specification defining a requirement for **[redacted]**. However, the product specification was not changed, and as a result, the revised manufacturing process was not validated, and no process monitoring was conducted. As of the inspection, **[redacted]** complaints hac been received involving tip dislodgements in catheters produced after the redesign of the tip. (See FDA-483 observation #6.)

7. Failure to identify all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3). In particular:

a. C/PAS 747, which covered detachment of Pt/Ir tips in Model 8731 Catheters, did not include an action to address 8731 Catheters that were in finished goods or already distributed. (See FDA-483 observation #7a.) (NOTE: These Model 8731 Intrathecal Catheters were eventually recalled by your firm on July 21, 2006.)

b. A field corrective action was not conducted until June 6, 2006, to address recurring Catheter Access Port (CAP) detachment failures in Synchromed EL

implantable infusion pumps. (See FDA-483 observation #7b.)

8 . Failure to implement procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality Systems regulation as required by 21 CFR 820.184. Specifically:

a. Traceability Cards for some Synchromed EL implantable infusion pumps did not include complete records of operations that were conducted under Manufacturing Process Variances or Product Review Requests (PRR's). (See FDA-483 observation #8a.)

b. A copy of process variance 1955, which covered **[redacted]** of Synchromed EL pumps, was not maintained in the documentation control system. (See FDA-483 observation #8b.)

This letter is not intended to be an all-inclusive list of deficiencies at your facility . It is your responsibility to ensure compliance with the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action to bring your products into compliance.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket approval applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct the deviations described in this letter. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

On July 24, 2006, we received an undated letter from George Aram, Vice President of Quality, Neurological Sector, which describes corrective actions taken and planned by your firm to address the FDA-483 Inspectional Observations. Only two of the corrective actions (for FDA-483 observations # 8 and 9) have been completed. Mr. Aram provided target completion dates for corrective actions to address the remaining FDA-483 Inspectional Observations, and he stated that monthly progress reports would be provided to our office beginning on August 28, 2006 . At this time, based on the limited information that has been provided, we are unable to determine whether your corrective actions are appropriate. In order to fully assess the implementation and effectiveness of the corrections, we will need to conduct a follow-up inspection.

[Redacted]

Please notify this office in writing within 15 working days to acknowledge receipt of this letter and to provide an update on the status of your corrective actions. Your response should be sent to Timothy G. Philips, Compliance Officer, at the address on this letterhead.

Sincerely,

/S/

W. Charles Becoat
Director
Minneapolis District

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